PACIFIC COAST OYSTER GROWERS ASSOCIATION

3582 '99 APR 20 A11:33

April 2, 1999

Dear Shellfish Growers and Friends of the Shellfish Industry,

The shellfish industry as we now know it will change dramatically if a petition currently before the U.S. Food and Drug Administration is accepted.

The petition, brought by the Center for Science in the Public Interest, seeks to require post-harvest treatment for all shellfish grown in areas with detectable levels of *Vibrio vulnificus*. ***This marine organism has been found in ALL coastal waters, including the West Coast, as the petition specifically points out.*** The petition would disallow shellfish sales (*potentially all shellfish, not just oysters*) wherever detectable levels of *Vibrio vulnificus* exist, or require the industry to post-harvest treat. The only currently FDA-accepted method for post-harvest treatment is a pasteurization process patented by the AmeriPure Company, which claims their process will add "only" 8 cents to the cost of each oyster. It is a costly yet effective method for killing both *Vibrios* and shellfish.

The petition also suggests FDA consider setting a new standard for *Vibrio parahaemolyticus* levels, noting that people have been known to become ill well below the current action level. The AmeriPure pasteurization process, the petition notes, works equally well in killing *Vibrio parahaemolyticus* bacteria.

FDA has chosen to respond to the CSPI petition by requesting public comments. They are under considerable political pressure from the non-profit CSPI, which has a strong and large subscriber base. They are highly effective in mounting campaigns of this sort, and we can be certain they will lobby their constituents to write letters to the FDA supporting the petition. Our ability to out-number their responses may well determine how FDA chooses to deal with this issue.

The deadline for receiving public comments is April 21, just three weeks away, so time is of the essence. I urge you and your friends, employees, neighbors and business associates to respond quickly, using the attached sample letter or in your own words. Also, call and/or write your congressional delegates and urge them to contact the FDA and insist they utilize the Interstate Shellfish Sanitation Conference as the appropriate means for developing public health policy.

If you need more information call me at 360-754-2744, E-mail at: pcoga@olywa.net, or call PCOGA President Steve Bloomfield at 360-426-9847.

Sincerely,

Robin Downey

Robin Downey
Executive Director

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Pacific Coast Oyster Growers Association
120 State Avenue NE #142 ♦ Olympia, Washington 98501 ♦ (360) 754-2744 ♦ Fax 754-2743 ♦ E-mail: pcoga@olywa.net

April 3, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Federal Register Request for Information: Performance Standard for Vibrio vulnificus Docket Number 98P-0504 -- Volume 64, Number 13, Page 3300-3301

Dear Mr. Hubbard,

The FDA has requested information on eight points of interest in regards to issues raised by a petition submitted by Center for Science in the Public Interest. The comments here will not address these eight points directly, although conclusions may be drawn through inference.

Public health policies should not be unilaterally developed by a federal agency based upon the demands of a single special interest group (i.e. CSPI). Rather, public health policy should be developed using the best available science within the framework of a collaborative forum. Policy and regulations developed in this manner best assure industry compliance which in turn best assures public health. This is the purpose of the Interstate Shellfish Sanitation Conference which is the appropriate mechanism for dealing with the issues brought forward by CSPI.

In 1998, regulators and the shellfish industry came together effectively at the ISSC to develop an Interim Control Plan for *V. parahaemolyticus* that set far stricter control measures for the industry than what is currently required. The control plan appears to have been effective on the West Coast: illnesses associated with *V. parahaemolyticus* virtually ceased when the industry voluntarily halted sales of oysters for raw consumption, as called for in the plan.

The control plan calls not only for stricter criteria on the part of the industry, it also calls for data collection and further research so that a sound scientific basis can be developed for formulating policy. It should be incumbent on FDA to promote and develop this research, rather than eliminating consumer choice. In the Federal Register request for information, the question is asked "do data exist that would permit the setting of a performance standard," and the answer is a resounding NO. The science for setting such standards does not currently exist. Not enough is known about strains of *V. parahaemolyticus* nor what constitutes an infectious dose.

I urge the FDA to refer this matter over to the ISSC for continued deliberation and at the same time provide the funding and research necessary to develop appropriate criteria for crafting public health policy.

Sincerely,

FDA's Eight Questions (From the Federal Register):

1. The AmeriPure Co. technology is not readily employable by the shellfish industry. Were this technology required, the vast majority of shellfish businesses on the West Coast would be forced out of business due to the cost.
2. There are no technologies I am aware of, including AmeriPure, that reduce V. vulnificus while retaining the sensory qualities of a raw oyster.
3. N/A – see #2
4. There is at present inadequate science available to determine what constitutes an appropriate performance level.
5. Establishing a performance standard for shellfish which do not pose a public health threat serves no public health purpose.
6. There is at present no way to determine what the costs would be for setting a performance standard, although ultimately any such standard would be borne by the shellfish industry, just as it would be if there was only a single, patented process available to meet such a standard.
7. AmeriPure would be the beneficiary of requiring performance standards.
8. Until the science exists to determine what constitutes an infectious doses for *V. parahaemolyticus*, the Interim Control Plan should be employed as the chief management tool while the industry and health regulators continue to fine-tune management strategies.

Under FDA's administrative regulations (21 CFR 10.30(h)(3)), the agency, when reviewing a petition, may employ various procedures, including publishing a Federal Register notice asking for information and views. Accordingly, FDA is hereby soliciting comment on the issues raised by the CSPI petition. However, FDA is especially interested in comments, with supporting data where appropriate, on the following questions:

1. Is the AmeriPure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of V. vulnificus in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of V. vulnificus to nondetectable levels?

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

4. Would a performance standard have to be as low as ``nondetectable?'' Do data exist that would permit the setting of a performance standard above ``nondetectable?'' If so, at what level? Should the fact that V. vulnificus is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

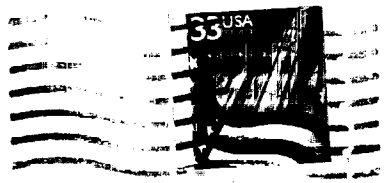
6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on costs be if a standard of ``nondetectable'' were put in place for all pathogens or for all raw molluscan shellfish?

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

8. Another marine pathogen, V. parahaemolyticus, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from V. parahaemolyticus have occurred from oysters harvested outside of the Gulf of Mexico region.

Should a performance standard apply only to V. vulnificus or should it apply to other Vibrio species that post-harvest treatment might be able to reduce to nondetectable levels?

WESTWIND SHELLFISH
2309 54TH AVE SW
TUMWATER WA 98512



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William Hubbard
Packets Managment Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville MD 20852

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